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REMARKS

In the Office Action dated June 26, 2008, claims 1, 3, 4, 7-9, 11, 12, 14, 28, and 35-47 were pending, all of which were rejected.

Claims 1, 3-4, 8-9, 12, 14, 36-37, and 40-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,421,349 to Rodriguez et al. ("*Rodriguez*") in view of U.S. Patent No. 5,295,493 to Radisch, Jr. ("*Radisch*"), further in view of U.S. Patent No. 5,584,803 to Stevens et al. ("*Stevens*") and even further in view of U.S. Patent No. 6,086,548 to Chaisson et al. ("*Chaisson*").

Claims 28, 35, 38-39, 45, and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Rodriguez* in view of *Radisch*, further in view of *Stevens*, even further in view of *Chaisson*, and even further in view of U.S. Patent No. 6,165,140 to Ferrera ("*Ferrera*"). Claims 7 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Rodriguez* in view of *Radisch*, further in view of *Stevens*, even further in view of *Chaisson*, and even further in view of U.S. Patent No. 6,716,183 to Clayman et al. ("*Clayman*").

Independent claims 1 and 36 have now been amended. The Applicants submit that support for the amendments to claims 1 and 36 can be found, at a minimum, at paragraphs 56, 57, 68, and 75 and Figures 1, 3, 4, and 7.

The Office Action has failed to cite a single reference, or a combination of references, which teaches or discloses each of the elements found in independent claims 1 and 36. None of the six references cited by the Office Action teach or disclose a tip zone "having a single direction of curvature with a radius of curvature of from 5 to 20 mm" Moreover, none of the references, taken alone or in proper combination, teach or disclose a distal tip which can bump into the aortic valve without causing damage, as required by independent claims 1, 36, and 41.

For example, *Stevens* is directed towards a system for accessing a patient's cardiac anatomy and is specifically configured to penetrate, and pass

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through, the aortic valve. Accordingly, Applicants submit that *Stevens* teaches away from the use of a distal tip which can bump into the aortic valve without causing damage. Moreover, it would be improper to combine *Stevens* with any other references which does not penetrate or pass through the aortic valve.

MPEP § 2143.01.

Moreover, the teachings of *Radisch* and *Chaisson* are directed towards guide wires which are shaped to enter into other vessels, such as the right coronary artery or carotid artery, from the aortic arch region. For example, *Chaisson* teaches a guide wire with a distal end which can be “manipulated and rotated (using fluoroscopy) to enter the right subclavian artery (see FIG. 10).” (Col. 4:33-35). The distal portion of the guide wire in *Chaisson* is designed specifically to accomplish this task. In contrast, the independent claims require a distal portion which “can bump into the aortic valve without causing damage,” which is not designed to enter into other vessels from the aortic arch. As such, the Applicants submit that *Radisch* and *Chaisson* teach away from the guide wire as recited in the independent claims.

These and other deficiencies found in the cited references will be discussed in greater detail below.

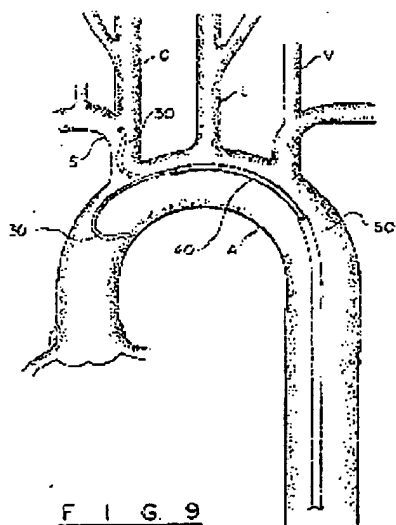
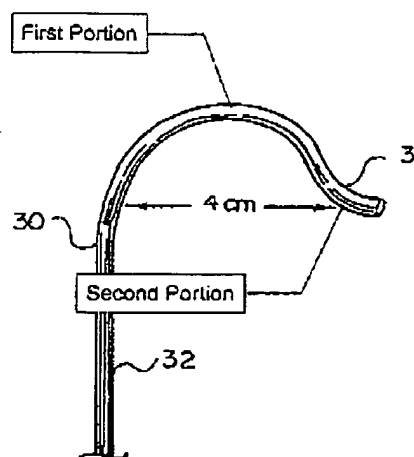
I. There is No Teaching or Disclosure of a “Tip Curve”

In addition to a pre-formed curve, amended claims 1 and 36 further require a “tip zone having high flexibility and having a tip curve having a single direction of curvature with a radius of curvature of from 5 to 20 mm, the high flexibility and the direction and radius of curvature being selected so that the tip curve can bump into the aortic valve without causing damage.” The Office Action cites that *Chaisson* teaches that “it is known to provide anatomical devices for insertion into a thoracic arch region of an aorta with a J-shaped distal tip having a radius of curvature of about 20 mm.” (Office Action, page 5). However, a closer look at

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Chaisson, and specifically Figures 5 and 9, shows no such tip curve at the distal end.

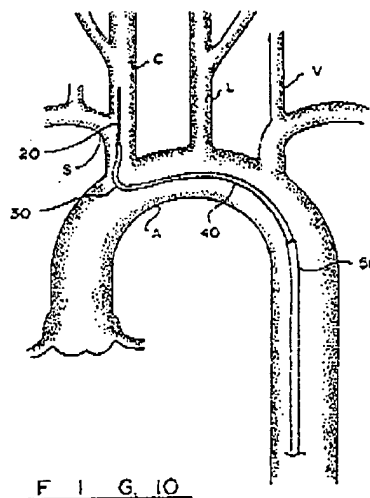


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Instead, as shown above, the distal end includes a first portion with a first direction of curvature and a second portion with a second, and different, direction of curvature. It does not disclose a tip curve having a single direction of curvature which can bump into the aortic valve without causing damage. Instead of being able to bump into the aortic valve, the distal end of *Chaisson* would pierce the valve, resulting in traumatic injury to the valve and the surrounding anatomy.

The specification is also devoid of any disclosure of a tip curve. The specification only states that "the free distal end 31 is connected to main portion 32 with a U-shaped portion having a radius of curvature of about 2 cm." (Col. 4:35-37). *Chaisson* is directed towards a carotid artery guiding system where the guide wire is designed to enter the carotid artery, as shown in Figure 10 below, and it does not disclose a tip curve which "can bump into the aortic valve without causing damage."



In fact, it would be counterintuitive for *Chaisson* to teach or disclose a tip curve without first direction of curvature and a second direction of curvature as it would be nearly impossible for an operator to be able to navigate the distal

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portion of the guide wire into the carotid artery with only a tip curve with a single direction of curvature. As such, *Chaisson* teaches away from the use of a tip curve.

Accordingly, and not surprisingly, there is no support in the specification or the figures for the proposition that the limitation found in claims 1 and 36 is taught or disclosed in *Chaisson*. Moreover, the addition of *Rodriguez*, *Radisch*, or *Stevens*, alone or in proper combination, does not cure this deficiency. It is for at least this reason that claims 1 and 36 are in allowable form.

Similar to claims 1 and 36, independent claim 41 requires, in part, "a first zone constituting a distal tip end and being very floppy and atraumatic, the distal tip end being configured to bump into the aortic valve without causing damage" This limitation, similar to the limitations found in claim 1 and 36, is not taught or disclosed in *Chaisson* for the reasons discussed above. The addition of *Rodriguez*, *Radisch*, or *Stevens*, alone or in proper combination, does not cure this deficiency. Accordingly, claim 41 is allowable for this reason alone.

The Applicants further submit that if, assuming *arguendo*, *Chaisson* does disclose a tip curve which "can bump into the aortic valve without causing damage," its teachings would be contrary to those of *Stevens*, and therefore would be improper to combine *Chaisson* and *Stevens*. *Stevens* is directed towards a system for accessing a patient's cardiac anatomy and is specifically configured to penetrate, and pass through, the aortic valve. Accordingly, it would not have been obvious at the time of the invention for one skilled in the art to combine a reference which prevents the penetration of the aortic valve with another reference which discloses a system to penetrate and pass through the aortic valve. *In re Grasselli and Hardman, and Rohm and Haas Co., Intervenor*, 218 U.S.P.Q. 769, 780 (Fed. Cir. 1983). Therefore, the Applicant's submit, should the Examiner determine that *Chaisson* does disclose a tip curve which

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“can bump into the aortic valve without causing damage,” it would not have been obvious to combine its teachings with those of *Stevens*. Accordingly, the Applicants respectfully submit that independent claims 1, 36, and 41 are in allowable form. Similarly, dependent claims 3, 4, 7-9, 11, 12, 14, 28, 35, 37-40, and 42-47 which depend from one of these independent claims are also in allowable condition for at least those same reasons.

II. None of the References Teach or Disclose the Claimed Zones of Stiffness

Claim 1 requires, in part, “a distal zone of transition of high stiffness to being relatively flexible . . . and being comprised of three zones: a semi stiff zone . . . a transition zone having flexibility of from semi-stiff extending to flexible; and a tip zone having high flexibility”

The Office Action states that the teachings of *Rodriguez* include “a distal zone being comprised of three zones: a semi stiff zone adjacent to the central zone; a transition zone having high flexibility of from semi-stiff to extending to flexible; and a tip zone having high flexibility” *Rodriguez*’s disclosure, however, regarding the flexibility of the distal end is limited to the following: “Guidewire 10 defines a distal tip 14, having a resilient, flexible tip which comprises a tapered down, thin portion 16 of the guidewire surrounded by a coil spring.” (Col. 2:66-68). *Rodriguez* does not teach or disclose the three zones within the distal zone or the respective stiffness of each of these zones. It is ambiguous as to whether the distal portion of *Rodriguez* would have three zones of stiffness, or whether the zones of stiffness would range from semi stiff to high flexibility, as claimed. Furthermore, the fact that the distal tip is also covered by a coil spring, which has independent resilient properties, further creates uncertainty as to the flexibility of the distal end. Accordingly, it is insufficient for the Office Action to rely on the teachings, or lack thereof, found in *Rodriguez*, to find that

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this limitation in claim 1 is disclosed therein. The addition of *Radisch*, further in view of *Stevens*, and even further in view of *Chaisson* does not cure this deficiency. For this reason alone, the Applicants' submit that claim 1 is in allowable form.

Similar to claim 1, claim 41 requires, in part, "a first zone constituting a distal tip end and being very floppy and atraumatic . . . a second zone, between the first zone and a third zone, being a transition zone going from floppy to semi-stiff; and a third zone . . . being a semi-stiff region" *Rodriguez* does not teach or disclose these three "zones" located at the distal portion of the guide wire for the same reasons as discussed above with respect to claim 1. Moreover, the addition of *Radisch*, further in view of *Stevens*, and even further in view of *Chaisson* does not cure this deficiency. For this reason alone, the Applicants' submit that claim 41 is also in allowable form.

III. Conclusion

In light of the above, Applicants submit that claims 1, 3, 4, 7-9, 11, 12, 14, 28, and 35-47 are in condition for allowance. A Notice of Allowance is respectfully requested.

The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

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